

REMARKS

I. Claim Status

Reconsideration of the present application is respectfully requested. Claims 1-9, 11-13, 15, 17, 31 and 32 are pending. Claims 10, 14, 16 and 18-30 have been canceled without prejudice. Claims 31 and 32 are new claims and encompass the subject matter of claims 14 and 16 as originally filed. Claim 1 has been amended to correct a typographical error. Claims 5, 7, 9, 11 and 13 have been amended to re-introduce subject matter that had been previously canceled due to the species election requirement. All amendments are supported by the specification and claims as originally filed, specifically originally filed claims 5, 7, 9, 11 and 13. No new matter has been added by way of this amendment.

II. Restriction Requirement

In response to the January 5, 2007 Restriction Requirement, Applicants previously elected Group I, claims 1-17. Pursuant to the species election requirement, Applicants elected Glucam P-20 as the species of emollient solvent; cationic hydroxy ethyl cellulose as the species of gelling or thickening agent; dimethiconal fluid in dimethicone as the species of silicone polymer; benzalkonium chloride as the species of antimicrobial agent; surfactant as the species of antioxidant or surfactant; and farnesol as the species of natural or synthetic compounds. The Examiner states that upon further consideration, the species election requirement has been withdrawn, and examination has been extended to other non-elected species. Thus, Applicants have amended claims 5, 7, 9, 11 and 13, and introduced new claims 31 and 32, to include the previously non-elected species.

III. Claim Objection

The Examiner has objected to claim 1 because the word "farsenol" is misspelled. Applicants have amended the claim to correct the spelling of the term to "farnesol." Applicants respectfully request that the objection be withdrawn.

IV. Rejections Under 35 U.S.C. § 103(a)

- A. U.S. Patent No. 5,985,918 to Modak et al. and U.S. Patent No. 6,344,218 to Dodd et al. in view of U.S. Patent No. 5,902,572 to Luebbe et al.

Claims 1-4, 6-8, 11-13, 15 and 17 stand rejected as unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,985,918 (to Modak et al.), and U.S. Patent No. 6,344,218 (to Dodd et al.), in view of U.S. Patent No. 5,902,572 (to Luebbe et al.). The Examiner contends that Modak describes topical formulations comprising water, emollients, excipients and organic salts of zinc in a concentration of between 0.1-15%. The Examiner further alleges that Dodd describes an aqueous deodorizing composition comprising an alcohol, a water-soluble metallic zinc salt, a thickener, an emollient, water, surfactants, and antimicrobial agents such as benzalkonium chloride, chlorhexidine and mixtures thereof. Finally, the Examiner states that Luebbe describes gel deodorant compositions comprising zinc salts and farnesol. According to the Examiner, it would have been obvious to an artisan of ordinary skill to combine the zinc composition of Modak with the antimicrobial composition of Dodd and the farnesol of Luebbe to form the anti-irritant composition described by the pending claims, thus rendering the claims obvious.

Applicants respectfully traverse the rejection and submit that the present claims are not obvious over the cited art. Applicants note that the Examiner's reliance on Modak and Dodd in rejecting the claims is commensurate with the Examiner's contentions in the previous office action. In the response to the previous office action, the claimed composition was amended to include an antimicrobial compound and farnesol, and Applicants further argued that the claimed composition provided for unobvious and unexpected advantages over Modak and Dodd. Subsequently, the Examiner has withdrawn the rejection of the claims as obvious over these two references. The Examiner now cites Luebbe as a secondary reference to provide a teaching of farnesol.

Applicants submit that evidence of unobvious or unexpected advantageous properties rebuts *prima facie* obviousness, and that the presence of a property not possessed by the prior art is sufficient evidence of nonobviousness. See MPEP 716.02(a); see also *In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963). The claimed invention encompasses, *inter alia*, the unexpected discovery

that zinc salts can be used at low concentrations to reduce irritation caused by creams or gels, while avoiding the systemic toxicity associated with compositions comprising high concentrations of water-soluble zinc salts. Furthermore, Applicants have also discovered that unlike compositions comprising high zinc salt concentrations, the low zinc concentrations of the invention do not interfere with the antimicrobial activity of antimicrobial agents present in the same composition. See page 8, paragraph 0019; and Examples 1 and 2, pages 28-31 of the specification.

As discussed in Example 5 of the instant application (see pages 36-37), antimicrobial compositions comprising a high concentration of zinc salts exhibit a reduction in the effectiveness of an antimicrobial agent present in the composition. Applicants have surprisingly discovered that when added to such a composition in low concentrations, zinc salts did not inhibit the effectiveness of the composition's antimicrobial agent. See Example 5, table 6, page 37 where the addition of 2% zinc gluconate to a composition had no effect on the ability of chlorhexidine gluconate to inhibit growth of *S. aureus*. Thus, low zinc salt concentrations can be used to reduce the irritation caused by a composition's ingredients, for example farnesol (see Example 13, pages 55-60), while still maintaining the effectiveness of a composition's antimicrobial agents. Additionally, Applicants have surprisingly found that an antimicrobial synergistic effect can be achieved by combining antimicrobial agents together in a single composition, and further, that such synergy is maintained when zinc salts are added to the composition at low concentrations. See Example 10, pages 47-52, where a composition comprising chlorhexidine gluconate, benzalkonium chloride and inicroquat exhibited antimicrobial synergy which was unaffected by the addition of zinc salts to the composition at low concentrations.

Applicants also submit that a high zinc ion concentration (e.g. 0.28% zinc ions), when introduced by a single species of zinc salt, can reduce the effectiveness of a spermicidal composition to which the zinc salt is added. In contrast, the present invention has surprisingly discovered that adding two or more zinc salts to a spermicidal composition, wherein the concentration of zinc ions from each independent zinc salt is low (e.g. 0.12% zinc ions from zinc gluconate and 0.14% zinc ions from zinc acetate) can reduce irritation caused by the spermicide while maintaining the spermicide's effectiveness. See Example 3, pages 31-32; and Example 4, pages 33-36 of the application.

Applicants submit that neither Modak nor Dodd disclose a composition comprising a low zinc salt concentration that is effective to prevent irritation while avoiding systemic zinc toxicity, or reducing the effectiveness of an antimicrobial agent present in the composition. Modak differs from the claimed invention by disclosing that creams comprising low zinc salt concentrations, such as those claimed by the instant application, are not capable of reducing irritation. *See* Modak, column 3, Table A of the Examples. Dodd includes zinc salts, along with antimicrobials such as chlorhexidine salts, benzalkonium chloride, and mixtures thereof, in a deodorant composition as odor control agents, but is silent with regard to the effect of low zinc salt concentrations on the efficacy of the antimicrobials. *See* Dodd, column 5, lines 60-67; and column 8, lines 8-27. Additionally, unlike the claimed invention, the cited references' failure to recognize the advantage of low zinc salt concentrations with regard to the efficacy of antimicrobial agents is further evidenced by their disclosure that zinc concentrations as high as 15% (*see* Modak, column 2, lines 27-29) and 10% (*see* Dodd, column 6, lines 17-19) may be used in the disclosed compositions.

Similar to Modak and Dodd, Applicants also submit that Luebbe fails to recognize that the use of zinc salts at low concentrations can ameliorate irritation without inducing systemic toxicity, or reducing the detergent effect of an antimicrobial agent. Rather, Luebbe teaches that farnesol and zinc salts are two of among many different agents that are useful as antimicrobial "deodorant actives," effective in preventing or eliminating malodor associated with perspiration when present in a deodorant formulation at a concentration of 0.001-50% by weight. *See* Luebbe column 1, lines 58-60; and column 3, lines 2-21. Thus, unlike the present invention, Luebbe fails to realize the advantage of using low concentrations of zinc salts in antimicrobial compositions to prevent irritation. As such, a skilled artisan would not have expected to achieve the surprising and unobvious results of the present invention by combining the teachings of the cited references. Applicants respectfully request that the rejection be withdrawn.

- B. U.S. Patent No. 5,985,918 to Modak et al., U.S. Patent No. 6,344,218 to Dodd et al. and U.S. Patent No. 5,902,572 to Luebbe et al. in view of U.S. Patent No. 4,868,169 to O'Laughlin et al. or U.S. Patent No. 5,073,372 to Turner et al.

The Examiner has rejected claim 5 under 35 U.S.C. § 103(a) as obvious over Modak, Dodd and Luebbe in view of U.S. Patent No. 4,868,169 (to O'Laughlin et al.). The Examiner has rejected claim 9 under 35 U.S.C. § 103(a) as obvious over Modak, Dodd and Luebbe in view of U.S. Patent No. 5,073,372 (to Turner et al.). As described above, the Examiner contends that Modak, Dodd and Luebbe disclose an anti-irritant composition comprising organic salts of zinc, an antimicrobial compound and farnesol. The Examiner further alleges that O'Laughlin describes creams which comprise the skin conditioner Glucam P-20, and that Turner describes facial emulsion formulations comprising organopolysiloxanes, including dimethiconol fluid in dimethicone. According to the Examiner, the compounds of O'Laughlin and Turner are useful as a skin conditioning agent and as an excipient in topical skin care compositions, respectively, and thus it would have been obvious to combine O'Laughlin's Glucam P-20 or Turner's dimethiconol fluid in dimethicone with the anti-irritant compositions of Modak, Dodd and Luebbe.

Applicants respectfully traverse the rejection and request reconsideration. As previously discussed, the claimed invention provides for unexpected and unobvious results. Specifically, Applicants have discovered that formulating an anti-irritant composition comprising an antimicrobial agent with low concentrations of zinc salts is effective to reduce irritation caused by the composition while avoiding the systemic toxicity and reduced antimicrobial activity associated with high zinc concentration compositions. Neither Modak, Dodd nor Luebbe suggest or describe an antimicrobial/anti-irritant composition comprising a low zinc salt concentration that can achieve the desirable reduction in irritation while avoiding the undesirable zinc systemic toxicity and reduction of antimicrobial activity.

Applicants submit that O'Laughlin is directed to oil-in-water steroidal cream formulations which are stable and do not undergo syneresis. *See* O'Laughlin column 22, lines 9-15. O'Laughlin provides no disclosure regarding zinc salts nor concentrations at which zinc salts are effective anti-irritants. O'Laughlin merely discloses Glucam P-20 as an optional skin conditioner for stable steroidal formulations.

Applicants further submit that Turner discloses facial formulations that prevent the appearance of oily skin by controlling the distribution of sebum (skin oil) across the face. Specifically, Turner discloses that dimethiconol fluid in dimethicone is useful for achieving such purpose. *See* Turner column 6, lines 33-56. Similar to O'Laughlin, Turner is silent with regard

to the effect of zinc salt concentration on preventing irritation or on the efficacy of antimicrobial agents. Thus, combining either O'Laughlin or Turner with Modak, Dodd, and Leubbe does not rescue the cited references' failure to provide a skilled artisan with an expectation that practicing the claimed invention would generate the surprising and unexpected results disclosed in the instant application. In view of the foregoing, Applicants respectfully request that the rejections be withdrawn.

V. Double Patenting

The Examiner has maintained the rejection of claims 1-9, 11-13, 15 and 17 on the grounds of nonstatutory obviousness-type double patenting over claims 1, 4-8, and 11-15 of U.S. Patent No. 5,965,610 to Modak et al. ("the '610 patent"). According to the Examiner, although the conflicting claims are not identical, they are not patentably distinct from each other because the "comprising" language of the '610 patent claims allows for the presence of other agents, including the antimicrobials and silicone polymers recited in the instant claims, and further because the instantly claimed concentrations are encompassed by the '610 patent claims.

The Examiner has maintained the rejection of claims 1, 3-9, 11-13, 15 and 17 on the grounds of nonstatutory obviousness-type double patenting over claims 1-3 of U.S. Patent No. 5,985,918 to Modak et al. ("the '918 patent"). According to the Examiner, the '918 patent claims a composition comprising zinc stearate and zinc salicylate in a "topical cream base." Although the conflicting claims are not identical, they are not patentably distinct from each other because, as contended by the Examiner, the "comprising" language of the '918 patent claims allows for the presence of other agents, including the thickeners, emollients, antimicrobials and silicone polymers recited in the instant claims.

Applicants respectfully submit that the appropriate action will be taken as the Examiner indicates allowable subject matter in the instant application.

The Examiner has maintained the rejection of claims 1-2 on the grounds of nonstatutory obviousness-type double patenting over claims 14-19 and 39-42 of copending Application No. 10/892,034. According to the Examiner, although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass compositions comprising two or more organic zinc salts. Because the allegedly overlapping claims have not yet been patented, this rejection is provisional. To the extent that claim scope overlaps in any


patented case, Applicants respectfully submit that the appropriate action will be taken as the Examiner indicates allowable subject matter in the instant application.

VI. Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be allowed and passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below. Applicants believe that no fee is due at this time. However, if any fees are required, the Commissioner is authorized to charge such fee to Deposit Account No. 02-4377.

Respectfully submitted,
BAKER BOTTS L.L.P.

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Sandra S. Lee
Patent Registration No.: 51,932
Attorney For Applicants

Lisa B. Kole
Patent Registration No.: 35,225
Attorney For Applicants

30 Rockefeller Plaza
44th Floor
New York, NY 10112-4498
(212) 408-2500
(212) 408-2501 (fax)